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| APPLICATION NO.          | FILI       | NG DATE    | FIRST NAMED INVENTOR        | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|--------------------------|------------|------------|-----------------------------|-------------------------|-----------------|
| 09/914,612               | 01/11/2002 |            | Neil Martin O'Brien-Simpson | 47-153                  | 9540            |
| 23117                    | 7590       | 11/28/2003 |                             | EXAMINER                |                 |
| NIXON & V                |            | HYE, PC    | ZEMAN, ROBERT A             |                         |                 |
| 1100 N GLEE<br>8TH FLOOR | BE ROAD    |            | ART UNIT                    | PAPER NUMBER            |                 |
| ARLINGTON, VA 22201-4714 |            |            |                             | 1645                    |                 |
|                          |            |            |                             | DATE MAILED: 11/28/2003 | 3               |

Please find below and/or attached an Office communication concerning this application or proceeding.

| ,   |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|
| -   | Application No.  | Applicant(s)   |  |  |  |  |  |
| Office Assign Summan  | 09/914,612   | O'BRIEN-SIMPSON ET AL.   |  |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit   |  |  |  |  |  |
| TI TANKING DATE ON THE COLUMN TO THE COLUMN | Robert A. Zeman  | 1645   |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address P riod for Reply  |  |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status   | 36(a). In no event, however, may a reply be till within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE   | mely filed ys will be considered timely. Ithe mailing date of this communication. ED (35 U.S.C. § 133).  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 11 Ja  | anuary 2002.   |  |  |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) This  | action is non-final.   |  |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |  |  |  |  |  |  |
| Disposition of Claims   |  |  |  |  |  |  |  |
| 4)  Claim(s) 1-18 is/are pending in the application.  4a) Of the above claim(s) is/are withdray  5)  Claim(s) is/are allowed.  6)  Claim(s) is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) 1-18 are subject to restriction and/or expressions.  | vn from consideration.   |  |  |  |  |  |  |
| Application Papers  | ·  |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examine   | r.   |  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |  |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Ex  | aminer. Note the attached Office   | Action or form PTO-152.  |  |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |  |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list 13) Acknowledgment is made of a claim for domestic since a specific reference was included in the first 37 CFR 1.78.  a) The translation of the foreign language pro 14) Acknowledgment is made of a claim for domestic reference was included in the first sentence of the  | s have been received. s have been received in Applicate ity documents have been received (PCT Rule 17.2(a)). of the certified copies not received priority under 35 U.S.C. § 119(a) to sentence of the specification of the specification of the priority under 35 U.S.C. §§ 120 | ion No  ed in this National Stage  ed.  e) (to a provisional application)  r in an Application Data Sheet.  ceived.  and/or 121 since a specific |  |  |  |  |  |
| Attachment(s)   |  |  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informal F  | (PTO-413) Paper No(s) Patent Application (PTO-152)   |  |  |  |  |  |

Art Unit: 1645

## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 3-8 and 10-11, drawn to peptides comprising SEQ ID NO:1 and compositions comprising said peptides.

Group 2, claim(s) 1-11, drawn to peptides comprising SEQ ID NO:2 and compositions comprising said peptides.

Group 3, claim(s) 1-11, drawn to peptides comprising SEQ ID NO:3 and compositions comprising said peptides.

Group 4, claim(s) 1 and 3-7, drawn to peptides comprising SEQ ID NO:4 and compositions comprising said peptides.

Group 5, claim(s) 1 and 3-7, drawn to peptides comprising SEQ ID NO:5 and compositions comprising said peptides.

Group 6, claim(s) 1 and 3-7, drawn to peptides comprising SEQ ID NO:6 and compositions comprising said peptides.

Group 7, claim(s) 1 and 3-7, drawn to peptides comprising SEQ ID NO:7 and compositions comprising said peptides.

Group 8, claim(s) 2 and 8, drawn to peptides comprising SEQ ID NO:8 and compositions comprising said peptides.

Group 9, claim(s) 2 and 8, drawn to peptides comprising SEQ ID NO:9 and compositions comprising said peptides.

Group 10, claim(s) 2 and 8, drawn to peptides comprising SEQ ID NO:10 and compositions comprising said peptides.

Art Unit: 1645

Group 11, claim(s) 2 and 8, drawn to peptides comprising SEQ ID NO:11 and compositions comprising said peptides.

Group 12, claim(s) 12, drawn to diagnostic tests utilizing peptides comprising SEQ ID NO:1 and compositions comprising said peptides.

Group 13, claim(s) 12, drawn to diagnostic tests utilizing peptides comprising SEQ ID NO:2 and compositions comprising said peptides.

Group 14, claim(s) 12, drawn to diagnostic tests utilizing peptides comprising SEQ ID NO:3 and compositions comprising said peptides.

Group 15, claim(s) 12, drawn to diagnostic tests utilizing peptides comprising SEQ ID NO:4 and compositions comprising said peptides.

Group 16, claim(s) 12, drawn to diagnostic tests utilizing peptides comprising SEQ ID NO:5 and compositions comprising said peptides.

Group 17, claim(s) 12, drawn to diagnostic tests utilizing peptides comprising SEQ ID NO:6 and compositions comprising said peptides.

Group 18, claim(s) 12, drawn to diagnostic tests utilizing peptides comprising SEQ ID NO:7 and compositions comprising said peptides.

Group 19, claim(s) 13-14 and 16, drawn to antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

Group 20, claim(s) 13-14 and 16, drawn to antibodies specific for SEQ ID NO:2 and compositions comprising said antibodies.

Group 21, claim(s) 13-14 and 16, drawn to antibodies specific for SEQ ID NO:3 and compositions comprising said antibodies.

Group 22, claim(s) 13-14 and 16, drawn to antibodies specific for SEQ ID NO:4 and compositions comprising said antibodies.

Group 23, claim(s) 13-14 and 16, drawn to antibodies specific for SEQ ID NO:5 and compositions comprising said antibodies.

Group 24, claim(s) 13-14 and 16, drawn to antibodies specific for SEQ ID NO:6 and compositions comprising said antibodies.

Group 25, claim(s) 13-14 and 16, drawn to antibodies specific for SEQ ID NO:7 and compositions comprising said antibodies.

Art Unit: 1645

Group 26, claim(s) 15, drawn to diagnostic tests utilizing antibodies specific for SEQ ID NO:1.

Group 27, claim(s) 15, drawn to diagnostic tests utilizing antibodies specific for SEQ ID NO:2.

Group 28, claim(s) 15, drawn to diagnostic tests utilizing antibodies specific for SEQ ID NO:3.

Group 29, claim(s) 15, drawn to diagnostic tests utilizing antibodies specific for SEQ ID NO:4.

Group 30, claim(s) 15, drawn to diagnostic tests utilizing antibodies specific for SEQ ID NO:5.

Group 31, claim(s) 15, drawn to diagnostic tests utilizing antibodies specific for SEQ ID NO:6.

Group 32, claim(s) 15, drawn to diagnostic tests utilizing antibodies specific for SEQ ID NO:7.

Group 33, claim(s) 17, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing peptides comprising SEQ ID NO:1 and compositions comprising said peptides.

Group 34, claim(s) 17, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing peptides comprising SEQ ID NO:2 and compositions comprising said peptides.

Group 35, claim(s) 17, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing peptides comprising SEQ ID NO:3 and compositions comprising said peptides.

Group 36, claim(s) 17, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing peptides comprising SEQ ID NO:4 and compositions comprising said peptides.

Group 37, claim(s) 17, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing peptides comprising SEQ ID NO:5 and compositions comprising said peptides.

Group 38, claim(s) 17, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing peptides comprising SEQ ID NO:6 and compositions comprising said peptides.

Group 39, claim(s) 17, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing peptides comprising SEQ ID NO:7 and compositions comprising said peptides.

Group 40, claim(s) 18, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

Group 41, claim(s) 18, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

Group 42, claim(s) 18, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

Art Unit: 1645

Group 43, claim(s) 18, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

Group 44, claim(s) 18, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

Group 45, claim(s) 18, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

Group 46, claim(s) 18, drawn to methods of reducing the prospect of *P. gingivalis* infection utilizing antibodies specific for SEQ ID NO:1 and compositions comprising said antibodies.

The inventions listed as Groups 1-46 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group 1) comprises the first recited **product**, peptides comprising SEQ ID NO:1 and compositions comprising said peptides. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The special technical feature of each invention is the sequence of the peptide themselves. Since each peptide possesses a different sequence they possess differing chemical and immunological properties and hence are distinct.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1645

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

Art Unit: 1645

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman November 25, 2003